

**REMARKS**

The present claims have been rejected by Examiner as follows:

1. Claims 1-3, 5-8, and 10-13 are rejected as unpatentable over Yamamoto and Nagpal. The Board has affirmed the first ground of rejection, but denominated it as a new ground of rejection under 37 CFR § 1.196 (b).
2. Claim 2 is rejected as unpatentable over Smith and Sequeira in combination with Nagpal. Having concluded that the claims were unpatentable over Yamamoto and Nagpal, the Board did not reach this ground of rejection.

The Board has affirmed that Examiner has successfully made a prima facie case of obviousness. While Applicant does not agree with this allegation, this issue will not be dealt with further herein, but Applicant reserves the right to revisit this issue on further appeal, if necessary.

The present claims have now been amended such that the claims specify that the methods relate to “an effective amount of tazarotene and an effective amount of a high-potency corticosteroid”. Claims 12 and 13 are cancelled to eliminate the redundancy occurring as a result of the amendments to claims 1 and 6. Applicant now submits that, with these amendments, the specification of the present application now contains evidence of unexpected results, which are sufficient to overcome the obviousness rejection, notwithstanding any prima facie obviousness that Examiner and the Board may believe exists.

Referring to Example 1, and the accompanying Figures 2, it is clear that the combination of tazarotene and an high potency corticosteroid are surprisingly more efficacious than the other combinations tested, having a clear improvement over the other combinations virtually from the onset of the administration until reaching an advantage of about 15% over the next best treatment from 4 days until the end of the study. The Board stated that “the combination and tazarotene and a low-potency corticosteroid appear to provide

better results than the combination of tazarotene and a mid-potency corticosteroid in reducing the severity of psoriasis in patients over a period of 12 weeks.” The Board also observed “it appears that the combination of low-potency corticosteroid and tazarotene provides no better results than the combination of mid-potency corticosteroid and tazarotene”. According to the Board’s observations, increasing the potency of the corticosteroid has no apparent advantage in combinations up to mid-potency corticosteroids, thus it is surprising that the combination of tazarotene and a high-potency corticosteroid should have such a significant improvement over the other treatments. Figure 1 also shows a clinically significant reduction in plaque elevation for the tazarotene/high-potency corticosteroid combination compared to the other treatments.

The Board has alleged that “it is impossible to conclude from Table II that the incidence of adverse events was consistently lower in patients treated with mid- or high-potency corticosteroid in combination with tazarotene as compare with patients treated with low potency-corticosteroid in combination with tazarotene, or tazarotene alone.” While Applicant does not agree with this assertion, he submits that this assertion is not valid for the claims as they now stand. According to Table II, the adverse events associated with the tazarotene/high-potency corticosteroid combination is at least as low or lower, than the other combinations with the exception of burning. However, the trend in the total number of adverse events point to a significant advantage for the tazarotene/high-potency corticosteroid combination. Consider that the table below, which gives the total number of adverse events for each treatment, clearly shows a trend for reduced frequency of adverse events with higher-potency corticosteroids used in combination with tazarotene.

	Patients (%)			
	Taz/plac	Taz/low	Taz/med	Taz/high
Total Adverse Events	41	39	31	26

In light of the amendments made herein, and the aforementioned considerations, Applicant believes the claims are now patentable as they stand and respectfully request that the Examiner pass them to issue.

Respectfully submitted,



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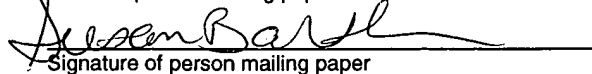
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**CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10**

I hereby certify that this Amendment and Reply and the documents referred to as enclosed herein are being deposited with the United States Postal Service on **October 28, 2003** in an envelope as "Express Mail Post Office To Addressee" mailing label number EV295682497US with sufficient postage for Express Mail addressed to Commissioner of Patents and Trademarks, P.O. Box 1450, Alexandria, VA 22313-1450.

Susan Bartholomew

Name of person mailing paper



Signature of person mailing paper

Date: October 28, 2003